**** D R A F T ****

Pesticide Registration (PR) Notice
August 2, 1999
Notice to Manufacturers, Producers, Formulators and Registrants of Pesticide Products

ATTENTION: Persons Responsible for the Registration and Reregistration of Pesticide Products

SUBJECT: Worker Risk Mitigation for Organophosphate Pesticides

I. Summary

This Pesticide Registration (PR) notice announces EPA's approach for managing risk to workers and handlers of organophosphate (OP) pesticide products. This approach generally provides for basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or protective clothing, as well as increased reentry intervals, for occupational situations where these measures are feasible and where current risk assessments indicate that they are necessary. Further, this notice outlines the steps that EPA intends take to address situations where baseline mitigation measures are not feasible, or situations where maximum feasible mitigation is still inadequate to protect workers.

The approach set out in this document is not final Agency action, but is intended solely as guidance. The notice itself does not impose binding obligations on either the registrants or EPA.

II. Background

The Agency is nearing completion of comprehensive risk assessments for the OP pesticides, as part of the larger process of implementing the Food Quality Protection Act of 1996 (FQPA) amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), and the ongoing process of reregistration established by FIFRA. The management of risks identified in the OP assessments is governed by two standards. The "reasonable certainty of no harm" standard in section 408 of the FFDCA, applies to the establishment and reassessment of tolerances, and governs all food uses. The "no unreasonable adverse effects on the environment" standard of FIFRA includes consideration of occupational and ecological risks. In managing these risks, EPA must take into account the economic, social, and environmental costs and benefits of the pesticide's use.

The implementation of the FQPA amendments has been the subject of a joint effort by EPA, USDA and interested stakeholders known as the Tolerance Reassessment Advisory Committee (TRAC). Among other initiatives, the TRAC has established a process for public participation in the review and refinement of risk assessments for the OPs and for developing risk management options. The public participation process consists of 6 phases. Phases 1 through 4 address the development and refining of the risk assessments. Phases 5 and 6 are concerned with the development and implementation of risk management plans. Much of the work of the TRAC has focused on dietary risk and tolerance reassessment. This notice is intended to augment the work of the TRAC by addressing management of the worker risk associated with the use of OPs.

The assessments for the organophosphate pesticides that have been completed thus far indicate that, with few exceptions, measures beyond those specified by EPA's Worker Protection Standard (40 CFR 170) appear to be needed to adequately protect workers and handlers of these products. The OP risk assessments in many cases show that, even with maximum feasible protective clothing and engineering controls (including all provisions currently required by the Worker Protection Standard), risks to workers still exceed the Agency's levels of concern. Although each OP risk assessment and any associated mitigation measures will be implemented on a case-by-case basis, the Agency is outlining its decision process in this notice because early notification to registrants will help to ensure that occupational risk management decisions for the OPs will be approached consistently and implemented equitably. The Agency also believes this early notification will encourage the voluntary adoption of measures to reduce risks to workers as soon as possible.

III. EPA's Approach to Occupational Risk Mitigation for OPs

A. Purpose

This notice is intended to provide manufacturers, producers, formulators and registrants guidance on the approach the Agency will take for the development of adequate, appropriate, and consistent risk mitigation for workers who mix, load, apply or handle OP pesticides, or crops treated with OP pesticides. As such, it provides manufacturers, producers, formulators, and registrants of OP pesticides advance notice concerning what measures are likely to be needed for their products and to plan ahead for the implementation of these mitigation measures. It is important to note that worker mitigation is only one part of the comprehensive mitigation options being developed during Phases 5 and 6 of the TRAC process. EPA also intends to develop mitigation for all risks of concern identified for each OP pesticide, including dietary, drinking water, residential and other non-occupational risks, and ecological impacts as well as occupational risk.

B. Scope

This notice addresses risks from occupational exposure to organophosphate pesticides from mixing, loading, and applying pesticides, as well as exposure from reentering treated fields

or greenhouses to harvest crops or undertake any other work in a treated area. The approach described in this notice applies to both workers and handlers as defined by the Worker Protection Standard (WPS), and other persons not specifically covered by WPS, who nonetheless perform similar activities and are exposed to pesticides in a similar manner. This notice is not intended to apply to residential, non-commercial uses of OP pesticides. The risks associated with residential and other non-occupational exposures are evaluated and addressed as part of tolerance reassessment under FFDCA sec. 408 (q).

EPA is particularly concerned for workers and handlers because of the relatively high risks predicted by current assessments, the acute toxicity of these compounds coupled with the large volume of chemicals handled and the potential for accidental exposure to concentrated products (i.e., products containing relatively high percentages of active ingredient).

While this notice focuses on workers exposed to organophosphate pesticides, EPA envisions that risks to workers exposed to other classes of pesticides with similar risks, e.g., carbamate pesticides, could be managed in a similar manner.

C. Worker Protection Standard

EPA's Worker Protection Standard for Agricultural Pesticides (WPS)-- 40 CFR Parts 156 and 170, is intended to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers who are occupationally exposed to pesticides. WPS affects all pesticide products whose labeling reasonably permits use in the commercial or research production of agricultural plants on any farm, forest, nursery, or greenhouse. The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted-entry intervals (REI), and notification are interim. These requirements are to be reviewed and revised, on a case-by-case basis, during reregistration and other Agency review processes.

D. Level of Concern

EPA estimates worker risk by evaluating occupational exposure levels, including both dermal and inhalation exposures, against the No Observed Adverse Effect Level (NOAEL) demonstrated in animal studies. The ratio of the estimated exposure to the NOAEL is referred to as the Margin of Exposure (MOE). Generally, MOEs that are greater than 100 do not exceed the Agency's level of concern for worker risk. An MOE of 100 represents a factor of 10X to account for differences in species sensitivity between animals and humans and another factor of 10X to account for differences in sensitivity to toxic effects within the human population.

For workers entering a treated site, restricted entry intervals (REIs) are calculated using a similar MOE approach to determine the minimum length of time required before workers or others are allowed to enter to perform routine hand labor activities.

E. Engineering Controls

For the purposes of occupational risk mitigation described in this notice, EPA anticipates that most occupational scenarios will require the use of some type of engineering control. In order to assist in defining what the Agency envisions by the term "engineering controls", several examples are given below. These items are not intended to suggest that a registrant will be required to incorporate all types of engineering controls simultaneously, but rather that these systems are currently known to the Agency as options.

1. Closed Mixing and Closed Loading

a. Closed Systems for Mixing and Loading. The engineering control available for mixing and loading pesticides is a closed system. By closed system EPA means a system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people while it is being handled. Under the WPS, when correctly using a closed system to mix or load pesticides, handlers need not wear all the personal protective equipment listed on the pesticide labeling for handlers.

When used correctly, water-soluble packaging qualifies as a closed loading system under the WPS. Handlers handling a product while it is enclosed in intact water-soluble packets are permitted to wear reduced PPE.

The only currently available type of closed system for use with wettable powder formulations is water-soluble packaging. A liquid pesticide may also be converted into a gel and packaged into water-soluble packets.

Another type of closed system for liquid formulations is a mechanical closed mixing system that consists of a probe that is inserted into the pesticide container and seals tightly to the pesticide container to prevent leaks, including vapors. The pesticide is either transferred to a spray tank or connected directly to the spray system. Mixers and loaders using this closed system are permitted to wear reduced PPE.

b. Mechanical Transfer System. A mechanical transfer system usually does not meet the definition of a closed system under the WPS. A Mechanical Transfer System is designed by the manufacturer to transfer liquid pesticide in a manner that prevents the liquid (but not necessarily any vapor) from contacting handlers or other people during the transfer. Since this system does not protect against inhalation exposures, it would generally NOT qualify as a closed system for chemicals with inhalation exposure concerns.

2. Enclosed Cabs

a. Enclosed Cabs for Application and Flagging. The engineering control available for applying pesticides in ground equipment and flagging to support aerial applications is an enclosed cab. By enclosed cab EPA means a cab having a nonporous barrier that totally surrounds the occupants and prevents contact with pesticides outside of the cab. Enclosed cab

systems that provide respiratory protection against dust/mist and/or organic vapors may, under some circumstances, substitute for respirators specified on the label. If inhalation is not a concern for ground applicators and flaggers (i.e., no respirator is required), any enclosed cab that surrounds occupants with a nonporous barrier meets the definition of enclosed cab and occupants need not wear all the PPE listed on the pesticide labeling.

b. Enclosed Cabs for Aerial Application. The engineering control available for applying pesticides in aerial equipment is an enclosed cockpit. Applicators in an enclosed cockpit may not, under some circumstances, be required to wear all the PPE listed on the pesticide labeling.

F. Rationale for Approach

The occupational risk assessments completed thus far for the OPs have shown that, with only a few exceptions, worker and handler MOEs for these pesticides exceed the Agency's level of concern (i.e., have MOEs < 100). In many cases, even with maximum personal protective equipment (PPE), such as chemical resistant gloves, coveralls and boots, or engineering controls, such as closed mixing and loading systems, calculated MOEs are still lower than 100. EPA has begun the process of developing mitigation strategies for some of the OPs.

While that process is ongoing, in the interest of product stewardship, the Agency encourages all registrants to consider amending their product labels to include the types of mitigation discussed in this notice. Technologies have been developed and are available to greatly reduce handlers' and workers' exposure. Many registrants are already providing their products in bulk and mini-bulk recyclable containers, water soluble packages, gel packs, and systems which, by nature of their design, prevent workers from having actual contact with the particular pesticide. In some cases, selection of the most appropriate systems is chemical-use specific and will depend on formulation type, application method and cost considerations. The Agency recognizes and welcomes innovative approaches that may be developed to suit specific needs and encourages registrants to consult with EPA on specific mitigation approaches.

G. Occupational Risk Management Approach for OPs

1. Based on the occupational assessments that have been conducted, EPA will first determine whether or not existing uses have adequate MOEs based on available data and current labeling. EPA considers worker risks greater than the target MOE, typically 100, to be not of concern. In such cases, the Agency is not planning to pursue additional risk reduction measures.

2. For uses with inadequate MOEs (generally < 100) based on current labeling, EPA will seek to reduce risks to workers to the greatest extent feasible with engineering controls and PPE, as well as application modifications such as decreased application rates. Based on the Agency’s experience with the OP occupational risk assessments completed thus far, this approach will likely include, at a minimum, the use of closed mixing and loading systems and enclosed cab equipment for pesticide application for most outdoor agricultural uses.

3. Where closed application systems are not feasible due to logistical constraints, for example, some greenhouse applications and some orchard applications under dense canopy, EPA intends to seek maximum feasible PPE which may include respirators, where appropriate, as well as modifications to use patterns. Because these types of application methods generally result in high exposure (and low MOEs) the Agency encourages suggestions for additional methods to reduce risk.

4. It is likely that exposures from certain application methods such as hand-held equipment, backpack sprayers, etc, can not be mitigated adequately by PPE or other measures.

5. Due to the availability of mechanical flaggers and Global Positioning Systems (GPS) the industry is moving away from the use of human flaggers. The Agency encourages registrants to revise labels to prohibit the use of human flaggers or restrict the use of human flaggers to enclosed cabs.

6. For harvesters and other workers reentering treated fields, if MOEs based on existing REIs are inadequate, EPA will extend REIs in order to provide adequate protection to these reentry personnel.

7. In situations where the MOEs are inadequate and risks continue to exceed benefits even after consideration of maximum PPE, engineering controls and modifications to the use pattern, the Agency will consider cancellation of the use.

This approach allows for consideration of a wide range of factors in making risk management decisions for worker risks. These factors may include, in addition to calculated MOEs, consideration of pesticide exposure incident data, the nature and severity of adverse effects, uncertainties in the risk assessment, the cost, availability and relative risk of alternatives, and the importance of the chemical in IPM programs.

H. Where to Send Label Amendments

Registrants who intend to amend their labels are encouraged to consult with EPA prior to submission.

Registrants who choose to amend their registrations at this time to incorporate worker and handler risk mitigation measures, may submit EPA Form No. 8570-1 Application for Pesticide Registration/Amendment and five copies of the revised label should be submitted for EPA approval. Send this application to:

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency

401 M Street, S.W.
Washington, DC 20460-0001

I. Implementation and Timing

Based on the current schedule, 3 OPs have entered the risk management phase (Phase 5) of the TRAC process as of August 2, 1999, 21 more will have entered Phase 5 by the end of this calender year; and the remaining 15 will enter during the year 2000. It is during Phase 5 that registrants and other stakeholders will work with the Agency to develop integrated risk management strategies for each chemical to address all the risks identified in the revised assessments.

In general, it is the Agency's expectation that risk mitigation agreed upon during Phase 5 of the TRAC process would be implemented as soon as possible. The Agency's goal is to have substantial worker mitigation in place for all of the OPs by December 31, 2000.

J. Existing Stocks

Provisions for existing stocks of OPs will be developed on a case-by-case basis and will be articulated once the individual chemical specific assessment is completed.

IV. For Further Information

A. Related Documents and How to Access Them

Preliminary and revised risk assessment for the OPs are available on EPA's web page (http://www.epa.gov/pesticides/op) and from the Office of Pesticide Program's (OPP) Public Docket. The OPP Docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Other documents related to the TRAC process and the schedule for completing the public participation process for the OPs are also available from these sources..

EPA encourages registrants and other interested parties to review the OP risk assessments currently available at the EPA web site or through the OPP Public Docket to determine which worker and handler situations are likely to require mitigation and which products may be affected.

B. Contact

Any questions regarding this notice or the Agency's approach for managing worker risks for the OPs should be directed to: Linda Werrell, Reregistration Branch II, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, US EPA, 401 M Street, SW, Washington, DC 20460; phone: (703) 308-8033; FAX: (703) 308-8041; e-mail: werrell.linda@epa.gov.

Marcia E. Mulkey

Director, Office of Pesticide Programs